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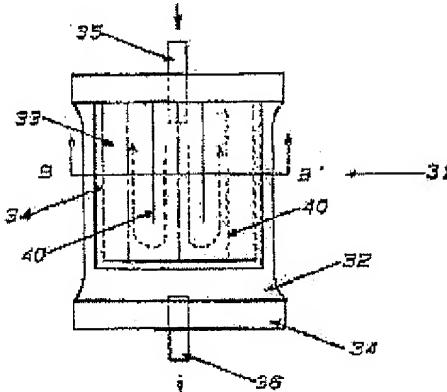
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(54) FILTER FOR REMOVING LEUKOCYTE

(57)Abstract:

PURPOSE: To obtain a filter for removing leukocytes useful for a medical supply such as a blood bag, a blood transfusion set, a blood circuit or a pheresis circuit and having high removing efficiency.

CONSTITUTION: [1] In this filter for removing leukocytes, a blood filter medium 33 consisting of fibers of $\leq 10 \mu m$ in fiber diameter whose periphery from the lower part to side part is sealed, is attached at the upper part of a flexible housing 32 which is provided with a blood inlet port 35 at the upper part and a blood outlet port 36 at the lower part. The housing 32 is divided into a blood flow-in section and a blood flow-out section and the blood flow-in section is connected to the blood inlet port and the blood flow-out section is connected to the blood outlet port. [2] In this filter for removing leukocytes, plural blood paths are formed by forming fused parts in the blood filter medium described in [1].



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CLAIMS

[Claim(s)]

[Claim 1] The filter for leukopheresis characterized by having loaded with the blood filtration material of 10micro or less of diameters of fiber into flexible housing, and welding said housing and periphery section.

[Claim 2] The filter for leukopheresis characterized by forming so that the tap hole of blood may be opened for free passage in the inflow room of blood at the input of blood, and the outflow room of blood, while loading with the blood filtration material of 10micro or less of diameters of fiber into flexible housing, welding the periphery section of said filter with said housing and classifying said housing into the inflow room and outflow room of blood.

[Claim 3] Cover a flank from the lower part, and the periphery section is sealed by the upper part of flexible housing which equipped the upper part with blood input and equipped the lower part with the blood tap hole, and it is equipped with the blood filtration material of 10micro or less of diameters of fiber. The filter for leukopheresis characterized by forming so that the tap hole of blood may be opened for free passage in the inflow room of blood at the input of blood, and the outflow room of blood, while classifying said housing into the inflow room and outflow room of blood.

[Claim 4] The filter for leukopheresis according to claim 3 characterized by having formed the welding in blood filtration material and forming two or more blood passage in blood filtration material.

[Claim 5] Claim 1 characterized by attaching PURERO fault material to blood filtration material thru/or the filter for leukopheresis given in four.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]**[0001]**

[Industrial Application] This invention relates to amelioration of the filter for leukopheresis used for medical supplies, such as a blood bag, a blood transfusion set, blood circuits, and a pheresis circuit.

[0002]

[Description of the Prior Art] Drawing 11 inserted the blood filtration material 133 which is the sectional view of the conventional filter 131 for leukopheresis, and consists of a nonwoven fabric or a filter of a porous body in the slot 137 of the housing 132 and 132 of the two-piece which consists of hard synthetic resin, by welding the edge 138 of housing 132 and 132, stuck the filter 133 by pressure and has prevented the leak from filter 133 end face (in drawing 11, 139 is a welding). However, if the thickness of a filter 133 became thick or the number of sheets of a filter 133 increased with housing only for being stuck by pressure physically, since the sticking-by-pressure force of a filter 133 would decline, the filter 133 fell, and the airtightness of a filter 133 caused blood leak from filter 133 end face. Moreover, when the sticking-by-pressure force of a filter 133 was made high, joining of housing 132 and 132 comrades became difficult, and was in the condition of being easy to damage the housing 132 after joining with residual stress. Furthermore, since a filter 133 was stuck by pressure, and housing 132 was fabricated with hard synthetic resin, shock resistance and chemical resistance were bad, imitated breakage by the crack by the chemical, the impact at the time of transportation, or fall, and were in it. Then, this invention person reached the next invention, as a result of repeating examination wholeheartedly, in order to solve the above technical problem.

[0003]**[Means for Solving the Problem]**

[1] This invention loads with the blood filtration material of 10micro or less of diameters of fiber into flexible housing, and offers said housing and the filter for leukopheresis which welded the periphery section.

[2] This invention loads with the blood filtration material of 10micro or less of diameters of fiber into flexible housing, welds the periphery section of said filter with said housing, and it offers the filter for leukopheresis formed so that the tap hole of blood might be opened for free passage in the inflow room of blood at the input of blood, and the outflow room of blood while it classifies said housing into the inflow room and outflow room of blood.

[3] Cover a flank from the lower part, the periphery section is sealed by the upper part of flexible housing with which the upper part was equipped with blood input and it equipped the lower part with the blood tap hole, and this invention equips it with the blood filtration material of 10micro or less of diameters of fiber. While classifying said housing into the inflow room and outflow room of blood, the filter for leukopheresis formed so that the tap hole of blood might be opened for free passage in the inflow room of blood at the input of blood and the outflow room of blood is offered.

[4] This invention offers the filter for leukopheresis given in [3] which formed the welding in blood filtration material and formed two or more blood passage in blood filtration material.

[5] This invention offers the filter for leukopheresis [1] which attached PURERO fault material to

blood filtration material thru/or given in [4].

[0004]

[Example] Drawing 1 is the schematic diagram (drawing 2 is the A-A sectional view of drawing 1) of the filter 1 for leukopheresis of this invention, and the filter 1 for leukopheresis is constituted by loading with the blood filtration material 3 into the flexible housing 2. Although the nonwoven fabric and porous body which are indicated by the fiber indicated by the public notice patent official report No. 54126 [Showa 58 to], for example and the open patent official report No. 193468 [Showa 60 to] as blood filtration material 3 are used, it is the nonwoven fabric which consists of a synthetic fiber or a synthetic fiber preferably, and housing which welds these further, and the thing to which the thermal property and the electrical property were similar are good. For example, although polyester, a polyamide, polypropylene, polyethylene, polyurethane, a polyvinyl chloride, acrylonitrile, a styrene system elastomer, etc. are used, the quality of the material in which the thermal resistance of 100 degrees C or more and autoclave sterilization are possible is desirable. Moreover, diameters of fiber, such as a nonwoven fabric which constitutes blood filtration material, have a 0.5 to 3 micro preferably desirable thing 10 micro or less. Distribution of these diameters of fiber may be uniform, and (the part [For example, being 5 etc. micro etc.] of arbitration 1 etc. micro etc.) may be uneven, and the mixture of homogeneity, homogeneity and homogeneity, an ununiformity and an ununiformity, and an ununiformity is sufficient as it. [the part of arbitration] These can be inserted between the flexible sheets of two sheets, and it can load into the flexible housing 2 by welding the periphery section (in drawing 1 , 4 is the seal section).

[0005] The flexible synthetic resin of housing 2 is good, and, as for blood filtration material, and thermal and the quality of the material which the electrical property of a like is good and is used for housing 2, the mixture of thermoplastic elastomer, such as a water garnish of an elasticity vinyl chloride, polyurethane, an ethylene-vinylacetate copolymer, and styrene-Butadiene Styrene, a styrene-isoprene-styrene copolymer, or its water garnish, and thermoplastic elastomer, and softeners, such as polyolefine and ethylene-ethyl acrylate, is hung up. Preferably, it is the thermoplastic agent elastomer which makes a principal component an elasticity vinyl chloride, polyurethane, styrene-Butadiene Styrene, a styrene-ethylene-butylene-styrene copolymer, and these.

[0006] Heat tracing joining by heat sealing is sufficient as joining of housing 2, and internal heating joining by the high frequency welder and the ultrasonic welder is sufficient as it. Moreover, joining only of the periphery section of the blood filtration material 3 which could be made to carry out joining to coincidence and carried out the laminating to it by heat sealing, the high frequency welder, and the ultrasonic welder may be carried out first, and, as for the method of joining, it may weld the blood filtration material 3 and housing 2 with housing 2 after that.

[0007] Moreover, while the blood input 8 and the blood tap hole 7 fabricate hard synthetic resin by injection molding and extrusion molding, it inserts between the flexible sheets of two sheets which constitute housing 2 and a flexible sheet is welded, it is also possible to equip housing 2. (In drawing 2 , 5 and 6 are regio-oralis weldings) . Finally these blood input 8 and blood tap holes 7 are equipped with the blood migration tubes 9 and 10. Moreover, it is also possible to replace with the blood input 8 and the blood tap hole 7, and to equip with the tip of the direct blood migration tubes 9 and 10. Housing 2 is formed so that it may be classified into inflow room 8a of blood, and outflow room 7a by the blood filtration material 3 and the tap hole 9 of blood may be open for free passage to inflow room 8a of blood at outflow room 7a of the input 8 of blood, and blood.

[0008] In the example of this invention, the nonwoven fabric made from polyurethane was used as blood filtration material 3, and it sealed with flexible synthetic-resin housing. The with a Shore A degree of hardness of 90 or less thing was used for flexible synthetic resin using a polyvinyl chloride and polyurethane (refer to Table 1).

[0009]

[Table 1]

| | |
|------|--|
| 実施例1 | ポリ塩化ビニル製ハウジング（硬度、ショア-A 90）にポリウレタン製不織布を入れ溶着した。 |
| 実施例2 | ポリ塩化ビニル（硬度、ショア-A 60）製ハウジングにポリウレタン製不織布を入れ溶着した。 |
| 実施例3 | ポリウレタン（硬度、ショア-A 90）製ハウジングにポリウレタン製不織布を入れ溶着した。 |
| 実施例4 | スチレン-ブタジエン-スチレン共重合体の水添物（硬度J I S D-43）製ハウジングにポリウレタン製不織布を入れ溶着した。 |
| 比較例1 | ポリカーボネート製（ロックウェル硬度、R 122）ハウジングにポリエスチル製不織布を入れ圧着した。 |
| 比較例2 | ポリプロピレン製（ロックウェル硬度、R 95）ハウジングにポリエスチル製不織布を入れ圧着した。 |
| 比較例3 | ポリ塩化ビニル製（硬度、ショア-95以上）ハウジングにポリエスチル製不織布を入れ圧着した。 |

[0010] The 200g iron ball was dropped from height of 1000mm for examples 1-4 and the examples 1-3 of a comparison, and the crack of housing was investigated for them. With the filter for leukopheresis of this invention, breakage was not seen from the result of Table 2.

[0011]

[Table 2]

| | 実施例 | | | | 比較例 | | |
|-----|------|------|------|------|-------|------|------|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 |
| 破損数 | 0/10 | 0/10 | 0/10 | 0/10 | 10/10 | 7/10 | 3/10 |

[0012] Drawing 3 is the schematic diagram (drawing 4 is A view Fig. of drawing 3) of the filter 11 for leukopheresis of this invention, and the filter 11 for leukopheresis is constituted by loading with the blood filtration material 13 into housing 12. It is loaded with the blood filtration material 13 into the housing 2 which consists of a flexible sheet of two sheets by using a plate-like thing (a monolayer -- and the laminating having been carried out -- it containing), for example, inserting between the flexible sheets of two sheets, and welding the periphery section with means, such as heat sealing, a high frequency welder, and an ultrasonic welder, (in drawing 3, 14 is a welding).

[0013] Thereby, the inside of housing 12 is divided by the blood filtration material 13 at the inflow room 18 and the outflow room 17 of blood, and it is formed in each ** 17 and 18 so that the input 16 of blood and a tap hole 15 may be open for free passage. A hole may be made in the flexible sheet which forms with injection molding and constitutes housing 12, and you may connect with it, or the input 16 of blood and a tap hole 15 may be connected to the flexible sheet which made the hole for the flexible tube-like thing.

[0014] The blood filtration material 13, selection of the quality of the material of housing 12, and seal can be performed like said filter 1 for leukopheresis.

[0015] In the example of this invention, the quality of the material of a filter, number of sheets, eyes thickness, the quality of the material of housing, the seal approach, etc. adopted the thing of a publication as Table 3 and Table 4. The pneumatic test, the shock-proof trial, and the leak trial were performed using the filter for leukopheresis indicated in the examples 6-10. The result is shown in Table 5. Also in which example, the good result was obtained from the result of Table 5.

[0016]

[Table 3]

| | 実施例6 | 実施例7 | 実施例8 | 実施例9 | 実施例10 | 実施例11 |
|---------|--------|--------|--------|----------|----------|--------|
| フィルター材質 | P・P | PE | SIS | PU | PU | PET |
| フィルター枚数 | 20 | 12 | 12 | 20 | 30 | 20 |
| ハウジング材質 | SEBS | SEBS | SEBS | PU | PVC | SEBS |
| 溶着方法 | ヒートシール | ヒートシール | ヒートシール | 高周波ウェルダー | 高周波ウェルダー | ヒートシール |
| 溶着状態 | ○ | ○ | ○ | ○ | ○ | × |

P・P ・・・・・ポリプロピレン

PE ・・・・・ポリエチレン

SIS ・・・・・ステレン-イソブレン-ステレン共重合体

PU ・・・・・ポリウレタン

PET ・・・・・ポリエスチル

SEBS ・・・・・ステレン-エチレン-ブチレン-ステレン共重合体

PVC ・・・・・ポリ塩化ビニル

[0017]

[Table 4]

| 実施例 | フィルター材質 | 目付 (g/m ²) | 厚さ (mm) |
|-----|-------------------------|------------------------|---------|
| 6 | P・P、ポリプロピレン製不織布 | 50 | 0.15 |
| 7 | PE、ポリエチレン製不織布 | 70 | 0.25 |
| 8 | SIS、ステレン-イソブレン-ステレン製不織布 | 100 | 0.25 |
| 9 | PU、ポリウレタン製不織布 | 50 | 0.36 |
| 10 | PET、ポリエスチル製不織布 | 50 | 0.15 |

[0018]

[Table 5]

| | 実施例6 | 実施例7 | 実施例8 | 実施例9 | 実施例10 |
|-------|-------|-------|-------|-------|-------|
| 気密試験 | もれなし | もれなし | もれなし | もれなし | もれなし |
| 耐衝撃試験 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 |
| リーク試験 | リークなし | リークなし | リークなし | リークなし | リークなし |

気密度試験…実施例6～10のフィルターを水中に入れ、0.4kg/cm²のゲージ圧で、空気送り込んだときの空気のもれを調べた。

耐衝撃テスト…実施6～10のフィルターに高さ1000mmより重さ200gの鉄球を落下させ、ハウジングの破損を調べた。

フィルターリークテスト…実施例6～10のフィルターに牛血を100ml/minで循環させフィルター端部からの血液リークを調べた。

[0019] Drawing 5 is the schematic diagram (drawing 6 is drawing of longitudinal section of drawing 5) of the filter 21 for leukopheresis of this invention, and the filter 21 for leukopheresis consists of blood input 25 with which the upper part of the housing 22 which welded the blood tap hole 26, and housing 22 is equipped. While the blood filtration material 23 is formed in hook bell shape, a flank is covered from the lower part and the periphery section is sealed by joining, opening of the upper part is carried out and joining of the upside edge is carried out to housing 22 (setting to drawing 5, 24 is the periphery seal section). Housing 22 is classified into the inflow room 28 and the outflow room 27 of blood, and it is formed so that the tap hole 26 of blood may be open for free passage in the inflow room 28 of blood at the input 25 of blood, and the outflow room 27 of blood. In order to equip with a suspending state, without sealing the periphery of the blood filtration material 23 on the periphery of

housing 22 in the filter 21 for leukopheresis at coincidence, a filtration area becomes large and a rate of filtration becomes quick. What has the quality of the material of housing 22 and the blood filtration material 23 the same as the filter 1 for leukopheresis is used.

[0020] The leukopheresis filter 31 of drawing 7 (drawing 8 is the B-B sectional view of drawing 7) forms a welding 40 in the lengthwise direction of the blood filtration material 33 (it corresponds to the blood filtration material 23 of drawing 5), and forms two or more blood passage 39 in the blood filtration material 33. Thus, since the regular blood passage 39 of a predetermined configuration is formed in the direction in which the swelling of the blood filtration material 33 can be controlled, and the blood of the blood filtration material 33 flows by forming a welding 40, a touch area with blood increases and the removal effectiveness of a leucocyte can be raised. Leukopheresis filter 31a of drawing 9 (C-C sectional view of drawing 10) is what formed welding 40a ranging from the side to the direction of slant of blood filtration material 33a, prevents the intense pressure near the center section of housing 32a by expansion of blood filtration material 33a, and blood filtration material 33a, and secures blood passage to the blood input 35a side. If the configuration of Weldings 40 and 40a is not limited to the thing of drawing 7 and drawing 9 and two or more regular blood passage can be formed in the blood filtration material 33 and 33a, it can adopt any configurations.

[0021] Moreover, the filters 1, 11, 21, and 31 for leukopheresis of this invention can attach the PURERO fault material 41 to the blood filtration material 3, 13, 23, and 33, as shown in drawing 2, drawing 3, drawing 6, and drawing 8. 60micro of diameters of fiber is filtration material with the large diameter of fiber in 5 to 30micro preferably from 3 in the PURERO fault material 41 as compared with the blood filtration material 3, 13, 23, and 33. Distribution of the quality of the material and the diameter of fiber is the same as that of said blood filtration material. Moreover, it can be made massive stratified and besides saccate and the flexible housing 2, 12, 22, and 32 can also be equipped. By attaching PURERO fault material, by filtrating whole blood to the blood filtration material 3, 13, 23, and 33 with an eye finer than the PURERO fault material 41 with a coarse eye, and two steps, the blinding of blood filtration material 3 grade decreases, and a leucocyte can be caught efficiently. In case the blood saved for a long period of time is filtrated, autotransfusion components, such as a congelation in blood (fibrin condensation matter) and adhesion matter, are caught by the PURERO fault material 41, the corpuscle which is in the meeting condition by the mothball can also be unfolded by the PURERO fault material 41, and mothball blood can also make it be the same as that of fresh blood, and they can do the separation activity of a constituent of blood efficiently.

[0022] Moreover, autoclave sterilization processing is all possible for the filters 1, 11, 21, 31, and 31a for leukopheresis of this invention.

[0023]

[Function and Effect of the Invention] By sealing blood filtration material with flexible housing, breakage of housing by the impact in the middle of transportation, fall, etc. can be prevented. Moreover, even if it carries out centrifugal to a blood bag and coincidence, breakage of housing and breakage of a blood bag can be prevented. Moreover, since joining of the periphery section of blood filtration material is carried out, even if the number of sheets which becomes thick or is piled up increases, airtightness does not fall or leak of blood etc. does not arise. Moreover, by forming a welding in blood filtration material, since regular blood passage is formed in blood filtration material while being able to control the swelling of blood filtration material and being able to lose stagnation of the blood in blood filtration material, a touch area with blood becomes large and can raise the removal effectiveness of a leucocyte.

[Translation done.]

【図6】図5の縦断面図

【図7】本発明の白血球除去用ロ過器の概略図

【図8】図7のB-B断面図

【図9】本発明の白血球除去用ロ過器の概略図

【図10】図8のC-C断面図

【図11】従来の白血球除去用ロ過器の断面図

【符号の説明】

1 白血球除去用ロ過器

2 ハウジング

3 血液ロ過材

4 密封部

5 口部溶着部

6 口部溶着部

7 血液流出口

8 血液流入口

7a 血液の流出室

8a 血液の流入室

9 血液移送チューブ

10 血液移送チューブ

11 白血球除去用ロ過器

12 ハウジング

13 血液ロ過材

*14 密封部

15 血液流出口

16 血液流入口

17 血液の流出室

18 血液の流入室

21 白血球除去用ロ過器

22 ハウジング

23 血液ロ過材

24 周縁密封部

10 25 血液流入口

26 血液流出口

27 血液の流出室

28 血液の流入室

31、31a 白血球除去用ロ過器

32、32a ハウジング

33、33a 血液ロ過材

34、34a 周縁密封部

35、35a 血液流入口

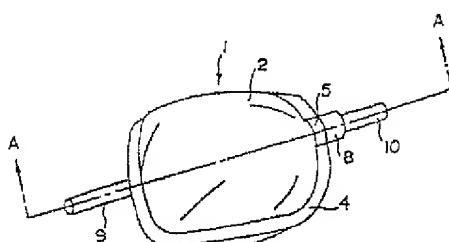
36、36a 血液流出口

20 39、39a 血液流路

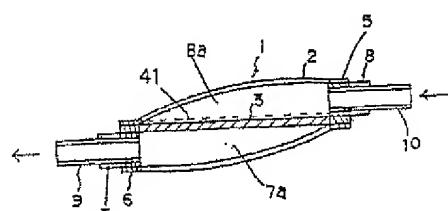
40、40a ロ過材溶着部(溶着部)

* 41、41a ブレロ過材

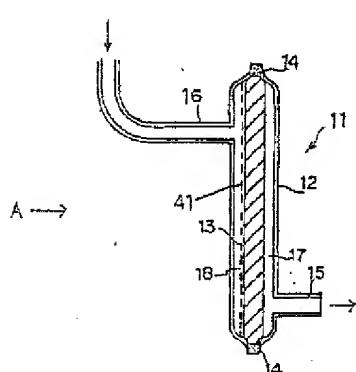
【図1】



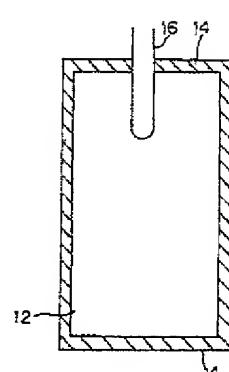
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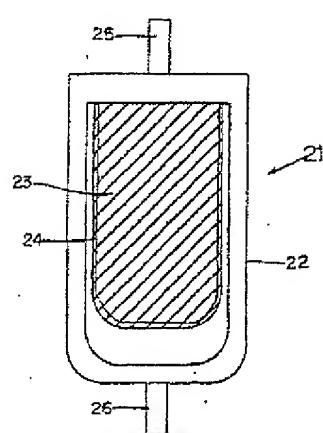
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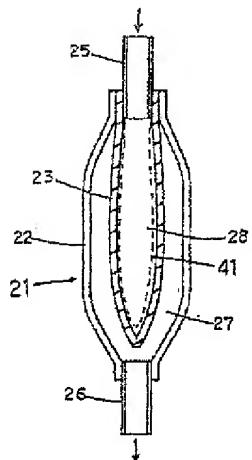
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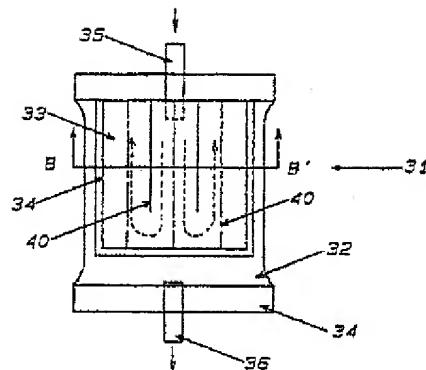
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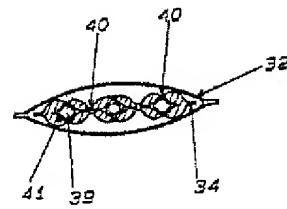
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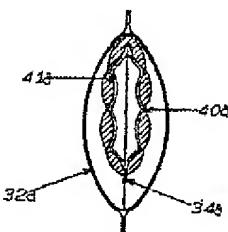
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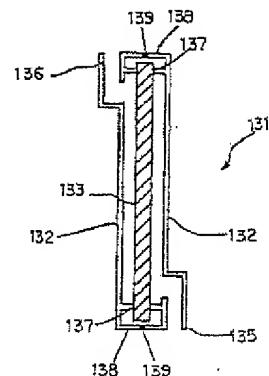
【図8】



【図10】



【図11】



【図9】

